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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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William A. Mittelstadt

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10/15/2009

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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3772

NOTIFICATION DATE

DELIVERY MODE

10/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/888,943 | Applicant(s) MITTELSTADT ET AL. | |
| | Examiner NIHIR PATEL | Art Unit 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-47 and 49-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-47 and 49-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

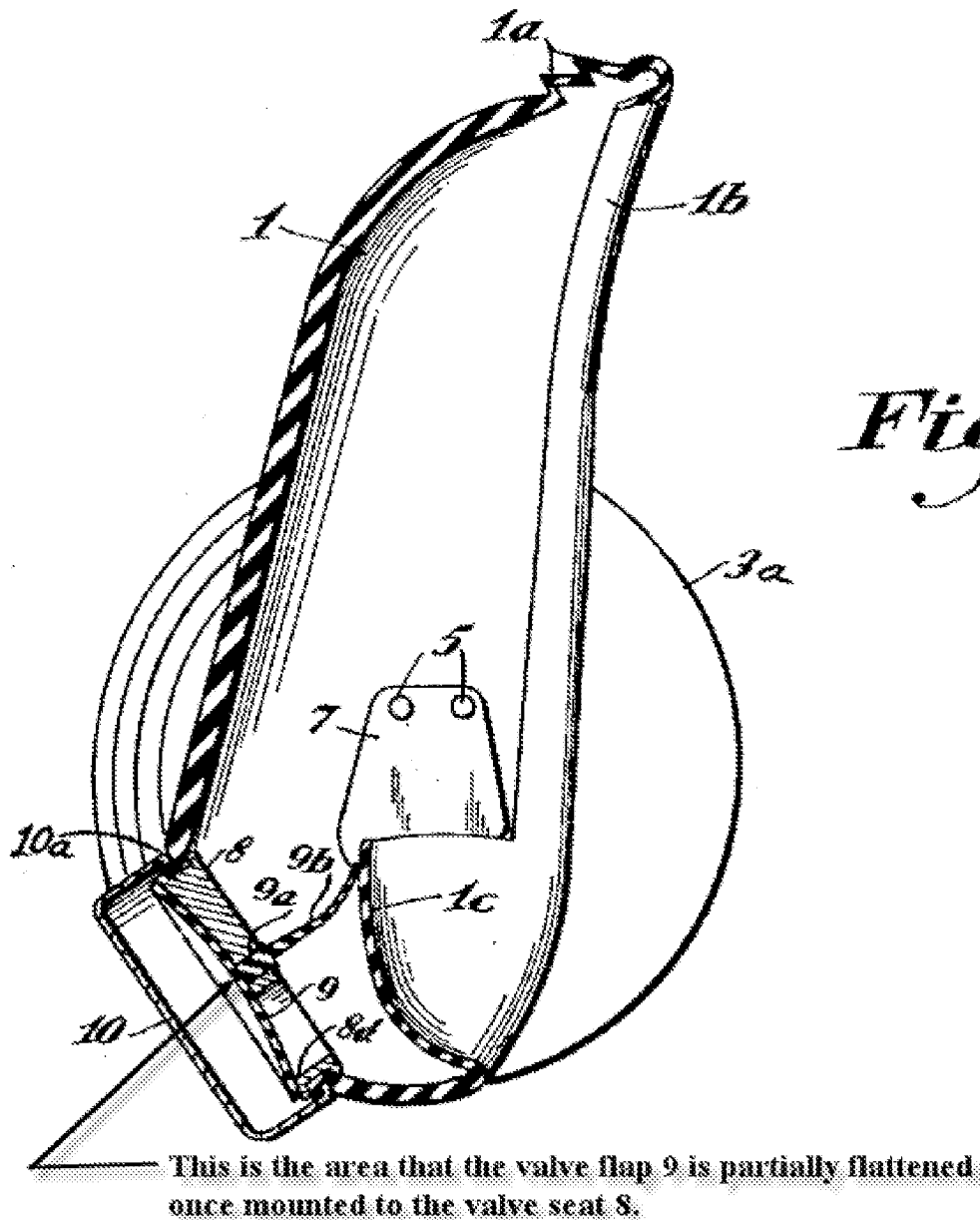
Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on July 14th, 2009 have been fully considered but they are not persuasive. In reference to claims 27-41 and 49-71 being rejected under 35 USC § 112 second paragraph, the applicant argues that there is no inconsistency in the claim language and that a person of ordinary skill can readily understand it. The applicant's explanation is not clear and the examiner believes there is inconsistency in the claim language and that a person of ordinary skill cannot readily understand it and therefore claims 27-41 and 49-71 are still rejected under 35 USC § 112 second paragraph.
2. The applicant further argues that nowhere does Matheson state that the valve flap becomes partially flattened once mounted to the valve seat. The examiner disagrees with the applicant's argument. Figure 2 below shows the valve flap becoming partially flattened once mounted to the valve seat.



Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims **27-47 and 49-71** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. As to claims **27-47 and 49-71**, first the applicant recites that a valve flap having a first portion attached to the valve body, then the applicant recites when the valve flap is not attached to the body. When the valve flap is attached to the valve body, how it is not attached. The applicant needs to make this clearer.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim **27-34 and 38-44** are rejected under 35 U.S.C. 102(b) as being anticipated by Matheson (US 2,999,498).

8. As to claim **28**, Matheson teaches an apparatus that comprises a face mask **1** (see **figs. 1 and 2; col. 2 lines 1-5**) having at least one opening for receiving a unidirectional valve (see **figs 1 and 2**); and a unidirectional valve comprising: a valve body comprising a valve opening (see **col. 3 lines 1-5; exhalation valve opening**); and a valve flap **9** having a first portion attached to the valve body (see **fig. 2**) and an adjacent second portion that seals the valve opening (see **fig. 2**), wherein the valve flap has a curvature from a first end to a second end when the valve flap is not attached to the valve body (see **fig. 6; col. 3 lines 10-20**), and further wherein at least a

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portion of the curvature of the valve flap is at least partially flattened when the valve flap seals the valve opening (**see fig. 2**).

9. **As to claim 27**, Matheson teaches an apparatus wherein the valve flap is removably attached to the valve body (**see col. 3 lines 15-25**).

10. **As to claim 29**, Matheson teaches an apparatus wherein the valve opening is generally planar, and wherein the valve flap curvature biases the valve flap toward the valve opening when the valve flap is attached to the valve body to seal the valve opening (**see fig. 2**).

11. **As to claim 30**, Matheson teaches an apparatus wherein the valve flap curvature biases the valve flap toward the valve opening to seal the valve opening, and wherein the bias of the valve flap toward the valve opening is sufficient to seal between the valve opening in any orientation of the unidirectional valve (**see fig. 2; col. 3 lines 15-25**).

12. **As to claim 31**, Matheson teaches an apparatus wherein the curvature in the valve flap comprises a constant curvature to the second end (**see fig. 6; when looking at the valve from the left side and the right side, there is a constant curvature towards the center of the valve**).

13. **As to claim 32**, Matheson teaches an apparatus wherein the curvature in the valve flap varies from the first end to the second end (**see fig. 6; when looking at the valve from left to right or vice versa you can see that the curvature increases than decreases defining different variation**).

14. **As to claim 33**, Matheson teaches an apparatus wherein the face mask is formed of a filtering material (**see col. 2 lines 40-45**).

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15. **As to claim 34**, Matheson teaches an apparatus wherein the unidirectional valve is an exhalation valve (**see col. 3 lines 1-15**).

16. **As to claim 38**, Matheson teaches an apparatus that comprises a face mask **1** (**see figs. 1 and 2; col. 2 lines 1-5**) comprising an opening formed therethrough (**see fig. 2; col. 3 lines 1-10**); and a unidirectional valve located over the opening in the face mask (**see fig. 2; lines 1-10**), the unidirectional valve comprising a valve flap **9** attached to the face mask over the opening, the valve flap comprising a curvature from a first end to a second end when the valve flap is not attached to the face mask (**see fig. 6; col. 3 lines 10-20**), wherein the curvature of the valve flap is at least partially flattened when the valve flap seals the opening in the face mask (**see fig. 2**).

17. **As to claim 39**, Matheson teaches an apparatus wherein the at least partially flattened curvature of the valve flap creates a bias that is substantial enough to keep the valve flap sealed over the opening in all orientations (**see fig. 2**).

18. **As to claim 40**, Matheson teaches an apparatus wherein the curvature in the valve flap comprises a constant curvature to the second end (**see fig. 6**).

19. **As to claim 41**, Matheson teaches an apparatus wherein the curvature in the valve flap varies from the first end to the second end (**see fig. 6**).

20. **As to claim 42**, Matheson teaches an apparatus wherein the opening is generally planar such that the curvature of the valve flap attached to the face mask over the opening is flattened when the valve flap seals the opening in the face mask (**see fig. 2**).

21. **As to claim 43**, Matheson teaches an apparatus wherein the face mask is formed of a filtering material (**see col. 2 lines 40-45**).

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22. **As to claim 44**, Matheson teaches an apparatus wherein the unidirectional valve is an exhalation valve (**see col. 3 lines 1-15**).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claims **35 and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Matheson (US 2,999,498).

26. **As to claims 35 and 45**, Matheson substantially discloses the claimed invention; see rejection of claims 28 and 38 above, but does not disclose a unidirectional valve that is an inhalation valve. It would have been an obvious matter of design choice to provide a unidirectional valve that is an inhalation valve in order to have better control of the amount of air being delivered to the user, since the applicant has not disclosed that having a unidirectional

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valve that is an inhalation valve solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with other types of valves.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772